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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/678,357	10/04/00	MARDH S	SMAR.P001

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HM22/0323

EXAMINER	
SHAHNAN-SHAH,K	
ART UNIT	**PAPER NUMBER**
1645	4

DATE MAILED: 03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/678,357	MARDH ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *Dec 21, 2000 preliminary amendment* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☒ The proposed drawing correction filed on *04 October 2000* is: a)☐ approved b)☒ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Detailed Action

1. Applicants preliminary amendment, received December 21, 2000, paper # 2 is acknowledged.

2. Currently claims 1-13 are pending.

Information Disclosure Statement

3. Substitute form 1449 and copies of references received 2/09/01. It is recommended to use PTO form 1449 for future references.

US patent number 5,074,594 not considered by the examiner, it described a Supermarket Price Tag System. The relevancy of this reference is requested.

Drawings

4. The drawings are objected by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 498.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 7 is rejected under the second paragraph of 35 U.S.C. 112 as being an improper dependent claim. Claim 7 broadens the scope of claim 4, from which it depends. Claim 4 is drawn to a Markush group consisting of 3 indicators. Claim 7

recites " The method of claim 4, wherein the group of indicators further includes an additional indicator comprising the level of pepsinogen I multiplied by the level of *Helicobacter pylori* antibodies, and wherein the level of this additional indicator is compared to a standard." thus improperly broadens the scope of claim 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lindgren et al. (European Journal of Gastroenterology and Hepatology, Volume 10, Number 7, pp 583-588 , July 1998)

Claims 1-8 are drawn to a screening method for gastritis, evaluting blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen I by immunoassay.

Lindgren et al. teach a screening method for gastritis, evaluting blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I) by immunoassay.

They further teach a method to compare the diagnostic performance of serum antibodies to H,K-ATPase, serum Pepsinogen A (same as Pepsinogen I) and the

Schilling test in diagnosing chronic atrophic body gastritis; to study the interrelationships between H,K-ATPase antibodies, serology for *Helicobacter pylori*, and gastric morphology. See table 1. , page 585.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 9-13 are rejected under U.S.C. 103 (a) as being unpatentable over Lindgren et al

Claims 9-13 are drawn to a kit for screening method for gastritis comprising reagents suitable for detecting H, K- ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Lindgren et al. teach a screening method for gastritis, evaluting blood samples for the presence of antibodies for H, K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I) . They also disclose that the antibodies to H, K-ATPase were determined using an enzyme- linked immunoabsorbent assay, *Helicobacter pylori* antibodies were dtetermined using enzyme immunoassy, and pepsinogen I serum level was determined by a double -

antibody radioimmunoassy. Lingren et al. did not teach a kit comprising the above reagents.

At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the reagents and methods taught by Lindgren et al. in form of a kit for screening gastritis.

8. Claims 1-13 are rejected under U.S.C. 103 (a) as being unpatentable over Oksanen et al. (Scandinavian Journal of Gastroenterology, Vol. 35, No. 8 pp 791-795, August 2000), in view of Ma J.Y. et al. (Scandinavian Journal of Gastroenterology, Vol. 29, No.11, pp961-965, 1994).

Claims 1-13 are drawn to a method and a kit for screening gastritis assaying blood samples for the presence of H, K- ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Oksanen et al. evaluated serum samples to predict normal gastric mucosa by studying the serum samples for *Helicobacter pylori* antibodies by enzyme immunoassy (Pyloriset EIA-G and EIA-A) and pepsinogen I was measured by an immunoenzymometric assay (Gastrotest PGI). Oksanen et al. did not teach assaying for H, K-ATPase antibodioes.

Ma J.Y. et al. studied sera from patients with pernicious anemia by means of enzyme-linked immunosorbent assay for the occurrence of antibodies against H, K-ATPase and *Helicobacter pylori* . Ma J.Y. et al. do not teach Elisa to measure pepsinogen I levels.

At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the two antibody assay methods and kits taught by Oksenen et al with the method taught by Ma J.Y. et al in form a kit for screening gastritis. The analysis of multiple analytes or more indicators associated with gastritis provides reliable method for diagnosing gastritis.

One of ordinary skill in art would have been motivated to do this in order to make a kit to simplfy and optimize diagnostic techniques to detect multiple antibodies in the same sample.

Additional art cited, but not used in this office action:

D'Angelo et al. (US patent number 5,989, 840).

Larka et al. (US patent number 5,932,430H)

Applemelk, BJ et al. (, Gut Vol.41(suppl.1) page A17, Sept.1997)

Oksanen, A et al (Journal of Clinical Microbiology, Vol 36, No.4 , pp 955-957, April 1998).

Shih et al. (Clininca Chemica Acta, Vol 175, pp 37-50 ,1988).

Matsumoto,K et al. (Journal of Clinical Pathology, Vol. 49, No. 12, pp.1005-1008 ,1996).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
3/22/01